

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AN05

Presumption of Service Connection for Amyotrophic Lateral Sclerosis

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations to establish a presumption of service connection for amyotrophic lateral sclerosis (ALS) for any veteran who develops the disease at any time after separation from service. This amendment is necessary to implement a decision by the Secretary to establish such a presumption based primarily on a November 2006 report by the National Academy of Sciences Institute of Medicine (IOM) on the association between active service and ALS.

DATES: Effective Date: This interim final rule is effective [Insert date of publication in the FEDERAL REGISTER]. Comments must be received on or before [Insert date 60 days after date of publication in the FEDERAL REGISTER].

Applicability Date: The provisions of this interim final rule shall apply to all applications for benefits that are received by VA on or after the effective date of this interim final rule or that are pending before VA, the United States Court of Appeals for Veterans Claims, or the United States Court of Appeals for the

Federal Circuit on the effective date of this interim final rule. In accordance with 38 U.S.C. 5110(g), the effective date of benefits awarded pursuant to this rule will be assigned in accordance with the facts found, but cannot be earlier than the effective date of this rule or the date one year prior to the date of application, whichever is later.

ADDRESSES: Written comments may be submitted through “www.Regulations.gov”; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW, Room 1068, Washington, DC 20042; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to "RIN 2900-AN05 – Presumption of Service Connection for Amyotrophic Lateral Sclerosis." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4923 for an appointment (this is not a toll-free number). In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at “www.Regulations.gov.”

FOR FURTHER INFORMATION CONTACT: Rhonda Ford, Chief, Regulation Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Ave., NW, Washington, DC 20420, (202) 461-9739.

SUPPLEMENTARY INFORMATION: This interim final rule establishes a presumption of service connection for ALS for any veteran who develops the disease at any time after separation from service. ALS (also called Lou Gehrig's disease) is a neuromuscular disease that affects about 20,000 to 30,000 people of all races and ethnic backgrounds in the United States and is often relentlessly progressive and almost always fatal. ALS causes degeneration of nerve cells in the brain and spinal cord that leads to muscle weakness, muscle atrophy, and spontaneous muscle activity. People suffering from ALS eventually lose the ability to move their arms and legs and to speak and swallow. The median survival period for people with ALS is 3 years from the onset of symptoms, and most people with ALS die from respiratory failure within 5 years. Currently, there is no effective treatment for ALS.

In November 2006, IOM issued the report *Amyotrophic Lateral Sclerosis in Veterans: Review of the Scientific Literature*, which concluded that “there is limited and suggestive evidence of an association between military service and later development of ALS.” The report summarized the findings of a 2005 “high-quality cohort study” by M.G. Weisskopf et al., entitled *Prospective study of military service and mortality from ALS*, 64(1) *Neurology* 32 (2005), which evaluated ALS risk among veterans with service prior to 1982, including veterans of service during World War II, the Korean War, and the Vietnam War, and concluded that these veterans, regardless of years of service, were at a

statistically significant greater risk of developing ALS compared to civilians. The IOM report concluded that “[a]lthough the study has some limitations . . . overall it was a well-designed and well-conducted study” that “adequately controlled for confounding factors (age, cigarette use, alcohol consumption, education, self-reported exposure to pesticides and herbicides, and several main lifetime occupations).”

The IOM report also noted that other studies corroborated the findings of the Weisskopf study, including 2003 studies by R.D. Horner et al. (*Occurrence of amyotrophic lateral sclerosis among Gulf War veterans*, 61(6) *Neurology* 742 (2003)) and R.W. Haley (*Excess incidence of ALS in young Gulf War veterans*, 61(6) *Neurology* 750 (2003)), which suggested that veterans of the 1991 Gulf War were at greater risk of developing ALS than civilians. IOM characterized the Horner study as “generally well conducted.” In December 2001, based on pre-publication announcements of these 2003 studies, Secretary of Veterans Affairs Anthony J. Principi made a policy decision to give special consideration to ALS claims by veterans of the 1991 Gulf War regardless of when the disease became manifest. The findings of the Weisskopf study, however, suggest that military service in general, and not just circumstances specific to the 1991 Gulf War, is related to the development of ALS.

The cause of ALS is unknown, but these studies indicate that there exists a statistical correlation between activities in military service and development of

ALS. Although the IOM report suggested that further studies may establish a more definite association between ALS and military service, the Secretary believes it is unlikely that conclusive evidence will be developed in the foreseeable future to establish the cause of ALS among military or civilian populations due to the rarity of this particular disease. After careful consideration of the studies referenced above and the fact that further research is unlikely to clarify this association between ALS and military service, the Secretary believes there is sufficient evidence indicating a correlation between ALS and activities in military service that supports establishment of a presumption of service connection for ALS for any veteran with that diagnosis.

Accordingly, the Secretary has decided to establish this presumption for ALS under his general rulemaking authority. Section 501(a)(1) of title 38, United States Code, provides that “[t]he Secretary has authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by [VA] and are consistent with those laws, including . . . regulations with respect to the nature and extent of proof and evidence and the method of taking and furnishing them in order to establish the right to benefits under such laws.” This authority is broad enough to encompass establishment of an evidentiary presumption of service connection under specified circumstances. In this case, the Secretary has determined that proof of active military, naval, or air service and the subsequent development of ALS is sufficient evidence to support a presumption that the resulting disability was incurred in the line of duty

during active military, naval, or air service, i.e., to establish entitlement to service connection. See 38 U.S.C. 1110.

Several circumstances unique to ALS warrant the establishment of a presumption of service connection for purposes of VA benefits. ALS is distinguishable from most other serious diseases because of its incurably debilitating, rapidly progressing, and invariably fatal characteristics. Most significantly, however, ALS is set apart from other diseases for purposes of establishing a presumption of service connection due to its statistically high development rate in veterans compared to the general population. Despite the high correlation with military service noted in the IOM report, the continuing uncertainty regarding specific precipitating factors or events that lead to development of the disease would present great difficulty for individual claimants seeking to establish service connection by direct evidence under generally applicable procedures in the absence of a presumption. This difficulty would be particularly profound in view of the rapid and devastating course of ALS and its impact on veterans and their families, which may inhibit their ability to participate in the development of evidence to support medically complex claims. Accordingly, the Secretary has determined that a presumption of service connection is warranted based on the available scientific and medical evidence and the unique circumstances surrounding ALS.

VA would welcome comments on any relevant peer-reviewed literature concerning ALS that has been published since the November 2006 IOM report. VA will continue to monitor developments in the scientific and medical fields concerning ALS. If, in the future, developments in the scientific and medical fields sufficiently establish that ALS is not associated with activities in military service, VA would revisit at that time the appropriateness of this presumption.

This interim final rule establishes a new § 3.318 to provide that the development of ALS at any time after discharge or release from active military, naval, or air service is sufficient to establish service connection for that disease. Paragraph (b) of new § 3.318 provides that this presumption of service connection for ALS does not apply if there is affirmative evidence that ALS was not incurred during or aggravated by such service or affirmative evidence that ALS was caused by the veteran's own willful misconduct. We recognize that there is very little likelihood that either of those standards will be met with regard to any particular claim, but we believe these provisions properly reflect Congress' intent, as expressed in 38 U.S.C. 1113, that evidentiary presumptions of service connection should not operate when there is affirmative evidence to the contrary or evidence of willful misconduct.

Paragraph (b) of new § 3.318 also provides that a presumption of service connection for ALS does not apply if the veteran did not have active, continuous service of 90 days or more. Although the Weisskopf study relied upon by the

IOM report concluded that veterans have an increased risk of developing ALS compared to civilians regardless of years of service, a minimum-service requirement of 90 days would not be inconsistent with the study's findings because the study focused on veterans' "years" of service and did not consider minimum periods of service. We believe that 90 days is a reasonable period to ensure that an individual has had sufficient contact with activities in military service to encounter any hazards that may contribute to development of ALS. Under 38 U.S.C. 1112(a) and 38 CFR 3.307(a)(1), the presumptions of service incurrence for various conditions, such as chronic diseases and tropical diseases, apply generally to eligible veterans with at least 90 days of active, continuous service. Thus, Congress considered 90 days to be the minimum period necessary to support an association between such service and subsequent development of disease. Consistent with that judgment, we believe that, for any shorter period, it is more likely than not that ALS was not associated with service.

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(3)(B) and (d)(3), we find that there is good cause to dispense with advance public notice and opportunity to comment on this rule and good cause to publish this rule with an immediate effective date. This interim final rule is necessary to implement immediately the Secretary's decision to establish a presumption of service connection for ALS for veterans with that

diagnosis. Delay in the implementation of this presumption would be contrary to the public interest.

Because the survival period for persons suffering from ALS is generally 5 years or less from the onset of symptoms, any delay would be extremely detrimental to veterans who are currently afflicted with ALS. Veterans with ALS may not be taking alleviating medications, participating in muscle and speech therapy, or receiving proper assistance for daily functions due to financial hardship or their lack of having service-connected status for their disability. Moreover, in all likelihood, some veterans will die from this rapidly progressive disease during a period for prior public comment. These veterans obviously would not receive any benefit from a presumption that is implemented after a public-comment period.

In order to benefit veterans currently suffering from ALS as quickly as possible, it is critical that VA establish this presumption immediately. For the foregoing reasons, the Secretary is issuing this rule as an interim final rule with immediate effect.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more

(adjusted annually for inflation) in any given year. This rule will have no such effect on State, local, and tribal governments, or on the private sector.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a “significant regulatory action” requiring review by the Office of Management and Budget, as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of entitlement recipients; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this interim final rule and has concluded that it is a significant regulatory action under Executive Order 12866 because it is likely to result in a

rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. The rule could affect only VA beneficiaries and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are as follows: 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Approved: August 1, 2008

James B. Peake,
Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity

Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

AUTHORITY: 38 U.S.C. 501(a), unless otherwise noted.

2. Add § 3.318 to read as follows:

§ 3.318 Presumptive Service Connection for Amyotrophic Lateral Sclerosis.

(a) Except as provided in paragraph (b) of this section, the development of amyotrophic lateral sclerosis manifested at any time after discharge or release from active military, naval, or air service is sufficient to establish service connection for that disease.

(b) Service connection will not be established under this section:

(1) If there is affirmative evidence that amyotrophic lateral sclerosis was not incurred during or aggravated by active military, naval, or air service;

(2) If there is affirmative evidence that amyotrophic lateral sclerosis is due to the veteran's own willful misconduct; or

(3) If the veteran did not have active, continuous service of 90 days or more.

(Authority: 38 U.S.C. 501(a)(1))

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